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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,657	03/16/2004	Kazutami Sakamoto	250521US0CONT	1130
22850	7590	02/09/2006	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			WILLIAMS, LEONARD M	
			ART UNIT	PAPER NUMBER
			1617	
DATE MAILED: 02/09/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/800,657	Applicant(s) SAKAMOTO ET AL.	
	Examiner Leonard M. Williams	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-12, 14-23 and 25-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-12, 14-23 and 25-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/14/2005 has been entered.

Status of Claims

As per the amendment submitted 11/14/2005, claims 13 and 24 are presently canceled and claims 9 and 20 have been amended. Claims 1-8 have been previously canceled. Claims 9-12, 14-23, and 25-30 are currently pending.

The examiner notes that on page 7 of the remarks the applicant's indicate that claim 23 is to be canceled. The claim set indicates that claim 24 is to be canceled. The examiner is following the amended claim set and assuming the canceling of claim 23 on page 7 was meant to be claim 24.

Response to Remarks/Amendment

The applicant's have amended claims 9 and 20 to include a broad variety of treatments selected from the group consisting of vasodilation, improvement of blood

circulation, enhanced antiplatelet-aggregating activity, antibacterial activity, acceleration of absorption at the digestive tract, renal function regulation, neurotransmitting activity, promotion of erection, promotion of learning and enhancement of appetite. The applicant's have added this amendment in order to overcome the examiner's assertion that the patient subset is met by Baldacci, and thus anticipates the currently claimed invention. The examiner wishes to further elucidate the invention of Baldacci to further demonstrate that there is an overlapping patient population even over the claims as amended. First, Baldacci, in the abstract, teaches the use of a composition comprising arginine pyrrolidone carboxylate and lysine pyrrolidone carboxylate in a method of immunomodulating capable of restoring depressed immunodefenses. In col. 1 lines 5-10, Baldacci teaches that the pharmaceutical composition can be used in methods of immunomodulating activity useful for both elderly people having depressed immunodefenses and in children especially those often taken ill by tonsilitis and consequently in all pathologies with altered immunodefenses. The examiner respectfully points out that the currently amended claims include a treatment of antibacterial activity. As a patient in need thereof of treatment of antibacterial activity, has an altered immune system, the immunomodulating activity of the compositions of Baldacci inherently anticipate the currently amended claimed limitation. Further the compositions of Baldacci are clearly intended for the treatment of all pathologies resulting in altered immunodefenses. For reasons stated in earlier office actions and further for reasons put forth above the 102(b) and 103(a) rejections are maintained.

The rejections are restated below. The rejections have been adjusted to reflect the claims as amended.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-12, 14-23, and 25-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Baldacci (US Patent No. 4581371).

Baldacci, in col. 1 lines 15-35 and claim 1, teach a method for restoring depressed immunodefenses comprising administering to a patient having depressed immunodefenses an immunomodulating composition comprising L-arginine, L-lysine, and their salts with L-2-pyrrolidone-5-carboxylic acid anticipating the "...method of...comprising administering...a composition comprising at least one compound selected from the group consisting of pyrrolidonecarboxylic acid, a pyrrolidonecarboxylic acid salt, and a pyrrolidonecarboxylic acid derivative" of claims 9 and 20, the "...method...wherein said composition further comprises arginine..." of claims 10 and 21, the "...method...wherein said arginine is selected from..." of claims 11 and 22, and the "...method...wherein said composition further comprises at least one medicine or cosmetic" of claims 12 and 23.

Baldacci, in col. 2 line 55 to col. 3 line 10, teach a pharmaceutical composition containing L-2-pyrrolidone-5-carboxylate of L-arginine (1 g, ~4% by weight), L-2-pyrrolidone-5-carboxylate of L-lysine (1g, ~4% by weight), potassium iodide, sodium benzoate, fructose, ascorbic acid, sodium metabisulfite, lemon flavor, and deionized water anticipating the "...method...wherein said composition is a pharmaceutical composition...": of claims 16 and 27, the "...method...wherein said pharmaceutical composition is in a form..." of claims 17 and 28, the "...method... wherein said pharmaceutical composition further comprises..." of claims 18 and 29 and the "...method...wherein said pharmaceutical composition further comprises..." of claims 19 and 30.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14-15 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldacci as applied to claims 9-13, 16-24, and 27-30 above, and further in view of Noel (U.S. Patent No. 5141964).

Baldacci is as set forth above.

Baldacci does not teach cosmetic compositions in the form of a lotion, an emulsion, a gel, a cream, or an ointment.

Noel, in example 3, teaches a cosmetic composition comprising chitosan, gluconic acid, pyrrolidonecarboxylic acid (0.7% by weight), glucosamine HCl, arginine (0.6% by weight), and absorbed water.

Noel, in col. 2 lines 20-30, that the cosmetic compositions may be used to formulate creams, gels, milks, body emulsions, and liquid soaps.

It would have been obvious to one of ordinary skill in the art at the time the invention was made that the Baldacci compositions could be used in the formulations detailed in Noel as Noel demonstrates the use of Balducci's compounds as evidenced by Noel example 3. One would have been motivated to use Balducci's compounds in Noel's formulations in order to increase the immunomodulating activities of Noel's cosmetic skin preparations.

The examiner respectfully points out the following from MPEP § 2112.01: "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function

or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Conclusion

This is a request for consideration of Application No. 10800657. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

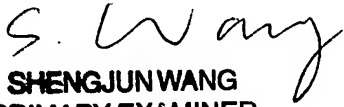
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LMW


SHENGJUN WANG
PRIMARY EXAMINER